



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-495]

#### **Schedules of Controlled Substances: Placement of *N*-Ethylhexedrone, *alpha*-Pyrrolidinohexanophenone, 4-Methyl-*alpha*-ethylaminopentiophenone, 4'-Methyl-*alpha*-pyrrolidinohexiophenone, *alpha*-Pyrrolidinoheptaphenone, and 4'-Chloro-*alpha*-pyrrolidinovalerophenone in Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** By this rule, the Drug Enforcement Administration permanently places six synthetic cathinones, as identified in this rule, in schedule I of the Controlled Substances Act. These six substances are currently listed in schedule I pursuant to a temporary scheduling order. As a result of this rule, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess) or propose to handle these six specified controlled substances will continue to apply.

**DATES:** Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-8207.

**SUPPLEMENTARY INFORMATION:** In this rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following six controlled substances, including their optical, positional, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the Controlled Substances Act (CSA):

- *N*-ethylhexedrone (other names:  $\alpha$ -ethylaminohexanophenone, 2-(ethylamino)-1-phenylhexan-1-one),
- *alpha*-pyrrolidinohexanophenone (other names:  $\alpha$ -PHP,  $\alpha$ -pyrrolidinohexanophenone, 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one),
- 4-methyl-*alpha*-ethylaminopentiophenone (other names: 4-MEAP, 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one),
- 4'-methyl-*alpha*-pyrrolidinohexiophenone (other names: MPHP, 4'-methyl-*alpha*-pyrrolidinohexanophenone, 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one),
- *alpha*-pyrrolidinoheptaphenone (other names: PV8, 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one), and
- 4'-chloro-*alpha*-pyrrolidinovalerophenone (other names: 4-chloro- $\alpha$ -PVP, 4'-chloro- $\alpha$ -pyrrolidinopentiophenone, 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one).

### **Legal Authority**

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General: (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);<sup>1</sup> or (3) on the petition of any interested party. 21 U.S.C. 811(a).

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<sup>1</sup> As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the Drug Enforcement Administration (DEA), and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. The regulatory controls and administrative, civil, and criminal sanctions for schedule I controlled substances on any person who handles or proposes to handle *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP will continue to apply as a result of this action.

## **Background**

The subject substances of this final rule are currently controlled in schedule I of the CSA by virtue of a temporary scheduling order (84 FR 34291, July 18, 2019) and an extension of that order (86 FR 37672, July 16, 2021). On July 16, 2021, pursuant to 21 U.S.C. 811(a), DEA published a notice of proposed rulemaking (NPRM) to permanently control these six synthetic cathinones in schedule I of the CSA. 86 FR 37719.

## **NPRM**

DEA's July 2021 rule proposed to permanently control *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP, and their optical, positional, and geometric isomers, salts, and salts of isomers in schedule I of the CSA. Specifically, DEA proposed to add these six synthetic cathinones to the hallucinogenic substances list under 21 CFR 1308.11(d)(94) through (99), respectively. The proposed regulatory text provided name(s) for these six substances as follows:

- *N*-ethylhexedrone (other name:  $\alpha$ -ethylaminohexanophenone),
- *alpha*-pyrrolidinohexanophenone (other names:  $\alpha$ -PHP,  $\alpha$ -pyrrolidinohexanophenone, 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one),
- 4-methyl-*alpha*-ethylaminopentiophenone (other names: 4-MEAP, 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one),

- 4'-methyl-*alpha*-pyrrolidinohexiophenone (other names: MPHP, 4-methyl-*alpha*-pyrrolidino hexanophenone, , 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one),
- *alpha*-pyrrolidinoheptaphenone (other names: PV8, 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one), and
- 4'-chloro-*alpha*-pyrrolidinovalerophenone (other names: 4-chloro- $\alpha$ -PVP, 4-chloro- $\alpha$ -pyrrolidinopentiophenone, 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one).

Regarding the substance *N*-ethylhexedrone, the preamble (Supplementary Information section) for the NPRM provided  $\alpha$ -ethylaminohexanophenone as well as multiple other names, including 2-(ethylamino)-1-phenylhexan-1-one.<sup>2</sup>

The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before August 16, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before August 16, 2021. DEA did not receive any comments.

### **Determination for Permanent Scheduling**

Based on the rationale set forth in the NPRM, the Administrator makes the findings, required under 21 U.S.C. 811(a) and 812(b)(1), for permanent placement of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the CSA. This final rule adds the six substances to the hallucinogenic substances list under 21 CFR 1308.11(d), and maintains their placement in schedule I. This final rule provides the same other names for all six specific substances, used in the regulatory text of the NPRM. In addition, this rule adds one other name, 2-(ethylamino)-1-phenylhexan-1-one,

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<sup>2</sup> In addition to  $\alpha$ -ethylaminohexanophenone and 2-(ethylamino)-1-phenylhexan-1-one, the NPRM preamble provided two other names (ethyl hexedrone and HEXEN).

for the substance *N*-ethylhexedrone. As discussed above, this additional other name was provided in the preamble for the NPRM.

### **Requirements for Handling *N*-Ethylhexedrone, $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-Chloro- $\alpha$ -PVP**

*N*-Ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP will continue<sup>3</sup> to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, and conduct of instructional activities involving the handling of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) or who desires to handle *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* *N*-Ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

3. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP

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<sup>3</sup> *N*-Ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP have been subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h), by virtue of the temporary scheduling order (84 FR 34291, July 18, 2019) and the subsequent one year extension of that order (86 FR 37672, July 16, 2021).

must be in compliance with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Every DEA registrant who possesses any quantity of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP was required to keep an inventory of all stocks of these substances on hand as of July 18, 2019, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

6. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding these substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP must continue to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP not authorized by, or in violation of the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

## **Regulatory Analyses**

### *Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

### *Executive Order 12988, Civil Justice Reform*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

### *Executive Order 13132, Federalism*

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The final rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

### *Executive Order 13175, Consultation and Coordination with Indian Tribal Governments*

This final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

### *Regulatory Flexibility Act*

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On July 18, 2019, DEA published an order to temporarily place *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 84 FR 34291. DEA estimates that all entities handling or planning to handle these substances have already established and implemented the systems and processes required to handle *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP. There are currently 34 unique registrations authorized to handle *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP specifically, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. From review of entity names, DEA estimates these 34 registrations represent 29 entities. Some of these entities are likely to be large entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 29 entities are small entities. Therefore, DEA conservatively estimates as many as 29 small entities are affected by this proposed rule.

A review of the 34 registrations indicates that all entities that currently handle *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, or 4-chloro- $\alpha$ -PVP also handle other schedule I controlled substances, and thus they have established and implemented (or maintain) the systems and processes required to handle *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP as a schedule I substance. Therefore, DEA anticipates that this final rule will impose minimal or no economic impact on any affected entities, and, thus, will not have a significant economic impact on any of the 29 affected small entities. Therefore, DEA has concluded that this final rule will not have a significant economic impact on a substantial number of small entities.



### *Unfunded Mandates Reform Act of 1995*

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year \* \* \* .” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

### *Congressional Review Act*

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the final rule to both Houses of Congress and to the Comptroller General.

### *Paperwork Reduction Act of 1995*

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

### *Determination To Make Rule Effective Immediately*

As indicated above, this rule finalizes the schedule I control status of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP that has already been in effect for over two years by virtue of the temporary scheduling order (84 FR 34291, July 18, 2019) and the subsequent one year extension of that order (86 FR 37672, July 16, 2021). The July 2019 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of

these substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1).

Because this rule finalizes the control status of *N*-ethylhexedrone,  $\alpha$ -PHP, 4-MEAP, MPHP, PV8, and 4-chloro- $\alpha$ -PVP that has already been in effect for over two years, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, DEA is making the rule effective on the date of publication in the *Federal Register*, as any delay in the effective date is unnecessary and would be contrary to the public interest. See 5 U.S.C. 553(d).

#### **List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

#### **PART 1308 – SCHEDULES OF CONTROLLED SUBSTANCES**

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. In § 1308.11, add paragraphs (d)(94) through (99) and remove and reserve paragraphs (h)(42) through (47).

The additions read as follows:

#### **§ 1308.11 Schedule I.**

\* \* \* \* \*

(d) \* \* \*

(94) *N*-Ethylhexedrone (Other names:  $\alpha$ -ethylaminohexanophenone; 2-(ethylamino)-1-phenylhexan-1-one).....7246

(95) *alpha*-Pyrrolidinohexanophenone (Other names:  $\alpha$ -PHP;  $\alpha$ -pyrrolidinohexanophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one).....7544

(96) 4-Methyl- <i>alpha</i> -ethylaminopentiophenone (Other names: 4-MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one).....	7245
(97) 4'-Methyl- <i>alpha</i> -pyrrolidinohexiophenone (Other names: MPHP; 4'-methyl- <i>alpha</i> -pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one).....	7446
(98) <i>alpha</i> -Pyrrolidinoheptaphenone (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one).....	7548
(99) 4'-Chloro- <i>alpha</i> -pyrrolidinovalerophenone (Other names: 4-chloro- $\alpha$ -PVP; 4'-chloro- $\alpha$ -pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one).....	7443
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**Anne Milgram,**  
*Administrator.*

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